Bringing Industry to Space: Commercial Space Life Sciences Research

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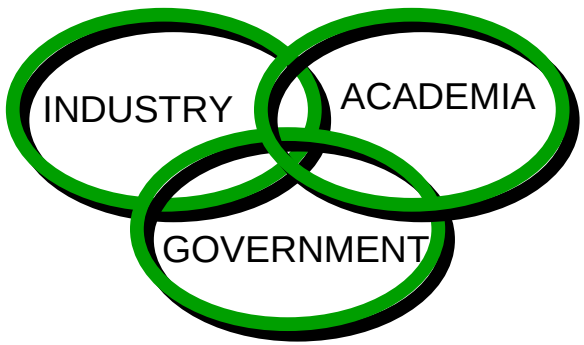
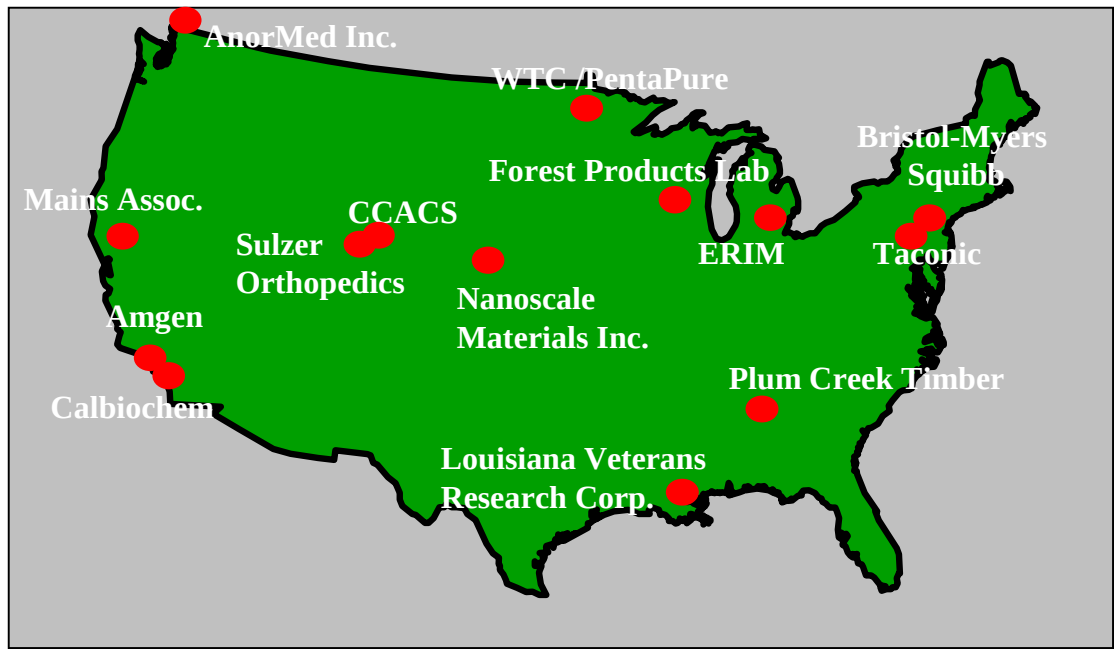
Mission

In partnership with industry, academia and government, develop new products and processes through space life sciences research.





The “Serve” in BioServe

- Frequent and productive access to space
- Substantial research expertise
- Unique facilities and low-gravity models
- BioServe intellectual property
- Marketing/business expertise

➢ But…….must also take leadership role in driving down costs and shortening timelines

Flight Research Cost Issue

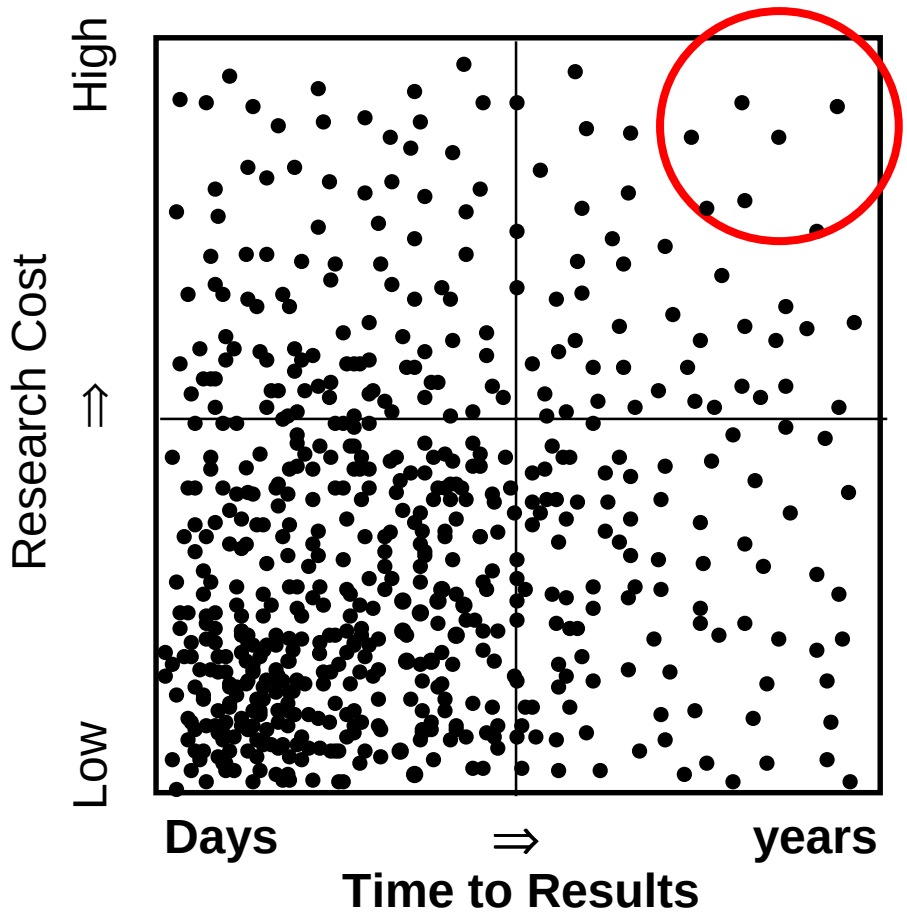
Category	Description	Relative Cost
1	Research (Ground studies and flight investigation)	$
2	Mission integration and operations (Analytical and physical)	$$$
3	Hardware development (Ground and flight experiment-specific hardware)	$$$
4	Transportation (Space Shuttle or any other means)	$$$$$
5	Use of on orbit resources (Crew time, power, heat rejection, data handling, communications, etc.)	$$$$$

Categories 1-3 alone can raise the cost 10-fold over comparable ground research

Flight Research Timeline Issue

- Product development timeline must be reasonable
  - Market opportunity may be lost to more rapid progress on other fronts
  - Challenge is especially great in life sciences due to dynamic nature of industry
- Period of time to first flight or between flights is 1-2 years or more
  - Due to length of time and level of effort required for mission integration
  - Due to competing priorities between scientific and other commercial research activities (backlog)
  - Multiple flights, if required, compound the challenge

Conducted Research



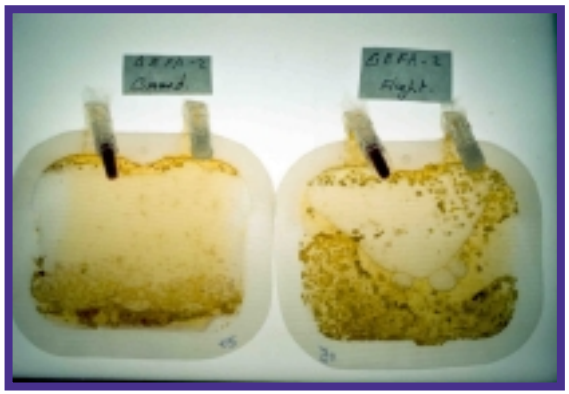
Strategies to Manage Cost

- Form research consortia
- Fly multiple investigations per mission
- Use generic hardware
  - Evolve capability over time
  - Multi-purpose, easily re-configured
  - Constant interfaces to spacecraft
- Minimize changes to the required documentation
- Accept some risk of experiment failures

Strategies to Manage Timeline

- Aggressively pursue flight manifesting
- Manifest w/o detailed knowledge of the experiment
  - Maintain flexibility to choose highest priority research
  - Allow investigator to optimize details of the research
- Minimize changes to the required documentation
- Consider variety of payloads and configurations to match to available resources

Microbial Pharmaceuticals



Actinomycin D Production on STS-95 (left is ground, right is flight, 75% increase)

- Estimated worldwide antibiotic market >$23B
- $20B in net sales and $1.8B in R&D in 1999 (BMS only)
- 1% increase in production efficiency ~$6.6M estimated annual cost savings

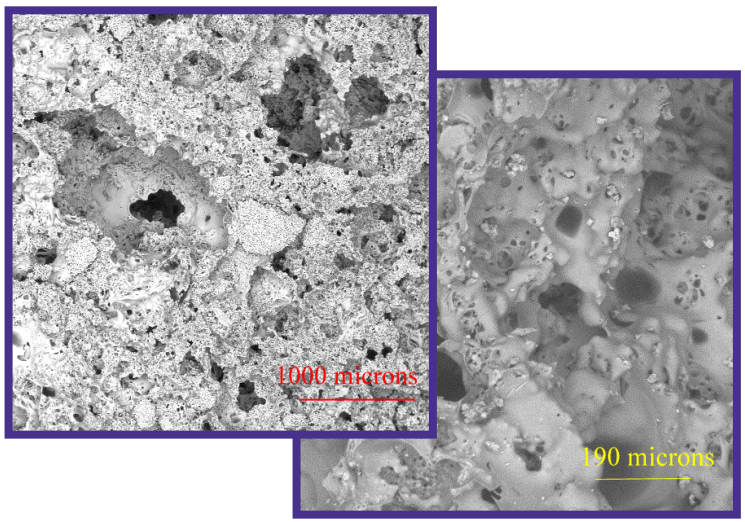
- Sponsored Project with Bristol-Myers Squibb
  - Project goal – Increase production efficiency of terrestrial facilities
- 3 shuttle flights to date that established research methodology and potential: STS-77, STS-80, STS-95
- Currently preparing second flight experiment for BMS on ISS Increment 4 (flight 8a)
  - Will study long duration fermentation processes

Improved Trees

- Wood and paper responsible for 8% of U.S. manufacturing output
- Benefits of reducing lignin by 10% in pulp feed stock would lead to:
  - 20-25% less energy use
  - 20% less CO_2 and other greenhouse gases
  - 25% less materials/chemical waste

- CRADA in place between USDA Forest Products Lab and BioServe
- Companies who have given commitments to research program:
  - Plum Creek Timber Co. (Georgia-Pacific)
  - International Paper
  - Weyerhauser
  - UPM-Kymmene
- Space research methodology established on STS-83/STS-94
- First long-duration mission planned for ISS (9A, 2002)
  - Model plant (Arabidopsis) to first be studied (gene expression, biosynthesis)
  - Harvesting time-course planned
- Loblolly pine to be flown in 2003

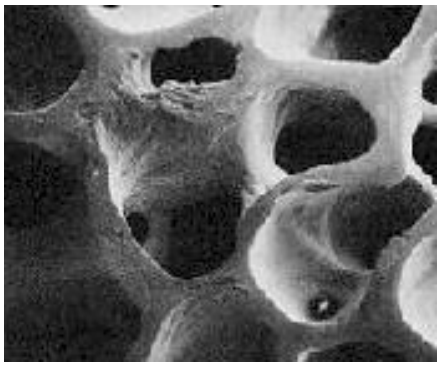
Porous Biomaterials

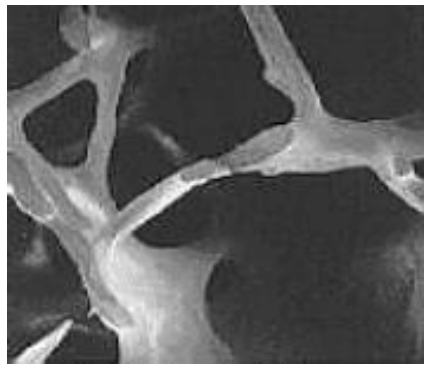


- Market Statistics
  - –Reconstructive Implants $5 billion worldwide ($2 billion US)
  - – 400,000 hip, knee, elbow, shoulder replacement cases in U.S. annually
  - –70% of all joint implants are placed in patients 65+

- Joint research project between CCACS and BioServe
- BioServe focus:
  - *in vitro* studies
  - *in vivo* studies
  - tissue engineering R&D
  - market analysis
  - business development
- Targeted Companies
  - Wright Medical Technology
  - Johnson and Johnson
  - Biomet
  - Sulzer Medica Orthopedics
  - Hewlett-Packard
- Research planned for ISS

Osteoprotegerin Efficacy



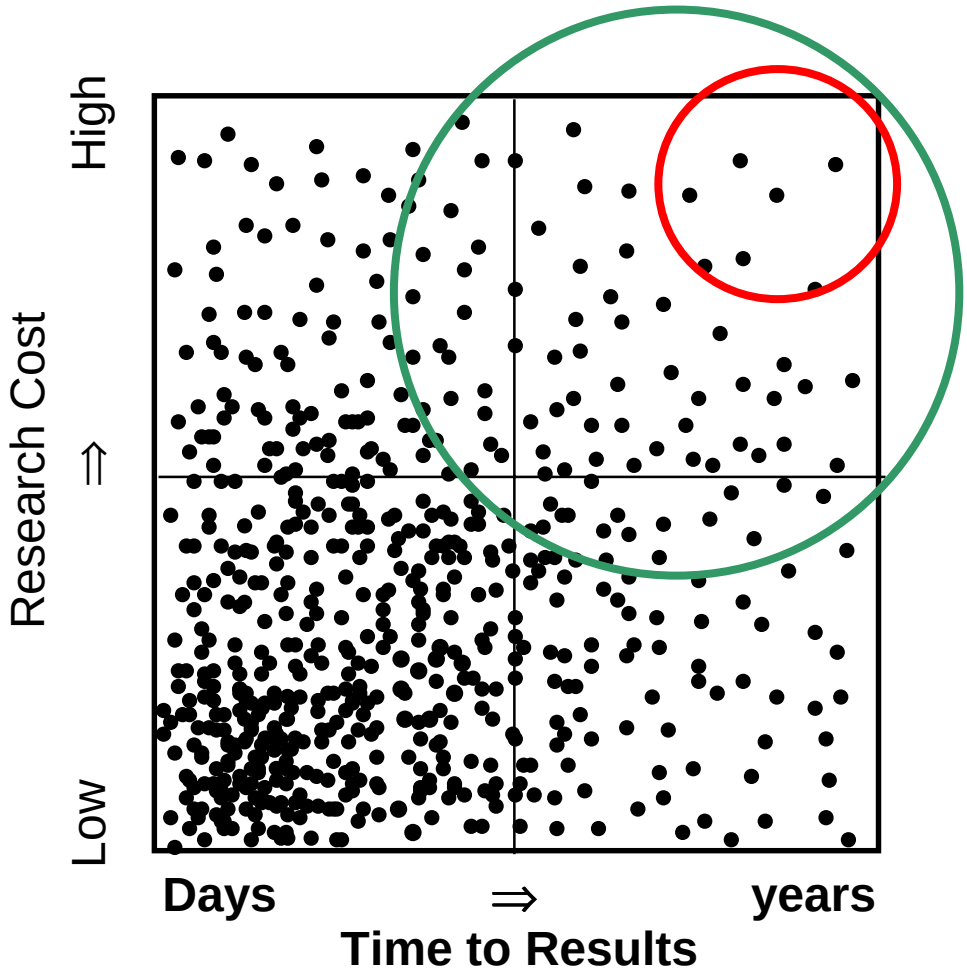


Normal bone (left) and osteoporotic bone (right). (www.nof.org, Dempster DW et al, J Bone Miner Res 1:15-21, 1986).

- Osteoporosis:
  - 10,000,000 cases in U.S.
  - 1 in 2 women will suffer fracture in life
  - 25,000 deaths due to complications
  - $14 Billion in medical costs annually
  - Major reduction in quality of life
- Current treatments with bisphosphonates or estrogen replacement are not ideal.

- Working with Amgen Corporation
  - Leading biotech company
  - First Fortune 500 in biotech
- OPG beginning Phase II Clinical trials
  - Metastatic bone cancer
  - Osteoporosis
- Ground studies at BioServe demonstrated efficacy of OPG
- First space flight evaluation to be done on UF-1 (2001)
- Future long-duration evaluation on ISS anticipated

Additional Barriers to Target



- Streamline integration process
- Eliminate redundancy or unnecessary flight requirements
- Increase number of payloads and samples transported to and from ISS
- Develop more on-orbit sample analysis capabilities
  - Data return vs. sample return
  - Reduce need for preservation systems and methodology
  - Requires more automated hardware AND crew time